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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/987,930	11/16/2001	Thomas P. Jerussi	4821-438-999	7891

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EXAMINER	
VU, JAKE MINH	
ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
03/05/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/987,930	JERUSSI ET AL.	
	Examiner	Art Unit	
	JAKE M. VU	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13,61-68,70-73,75-77 and 79* is/are pending in the application.

4a) Of the above claim(s) *68,71-73,75,77 and 79* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13,61-67,70 and 76* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *03/21/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of Applicant's Restriction Requirement Response filed on 12/03/2007; Information Disclosure Statement filed on 03/21/2007; Amendment and Request for Continued Examination filed on 06/06/2007.

- Claims 13, 61-68, 70-73, 75-77 and 79 are pending in the instant application.
- Claims 68, 71-73, 75, 77 and 79 are withdrawn from consideration.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06/06/2007 has been entered.

Election/Restrictions

Applicant's election of Group III (claims 13, 61-67, 70, and 76) and specie election of "salt" in the reply filed on 06/06/2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

/M. G. H./ Supervisory Patent Examiner, Art Unit 1618

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13 and 61-67 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant amended claims recite "(S,S)-2-(3-chlorophenyl)-3,5,5-trimethyl-**3**-morpholinol". However, from Applicant's footnote 1 on page 5 of the reply filed on 06/06/2007 and Applicant's specification, it seems Applicant meant to recite ""(S,S)-2-(3-chlorophenyl)-3,5,5-trimethyl-**2**-morpholinol", wherein "...3-morpholinol" should have been "…2-morpholinol". Please clarify.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 13, 61-67, 70, and 76 are rejected under 35 U.S.C. 102(e) as being anticipated by MORGAN et al (US 6,274,579).

Applicant's claims are directed to a method of treating a bipolar or manic condition which comprises administering to a patient 10-650mg per day of (S,S)-2-(3-chlorophenyl)-3,5,5-trimethyl-2-morpholinol or salt, wherein the composition is administered orally, transdermally, or mucosally.

MORGAN teaches a method of treating depression or ADHD (see abstract) which comprised administering to a patient 0.02 to 5mg/kg (see col. 5, line 38-42), in which an average 75kg man would need 1.5-375mg per day, of (S,S)-2-(3-chlorophenyl)-3,5,5-trimethyl-2-morpholinol or salt (see abstract), which is an active metabolite of bupropion (see col. 1, line 48 - col. 2, line 63) , wherein the composition is administered orally (see col. 5, line 59), transdermally (see col. 6, line 18), or buccal (see col. 5, line 60) which would read on mucosally. Additional disclosure includes: pure enantiomers of racemate (see col. 3, line 10-15).

Although the reference is silent about treating bipolar or manic condition, it does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. See *Bristol-Myers Squibb Company v. Ben Venue Laboratories,* 58 USPQ2d 1508 (CAFC 2001). "It is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable." *In re Woodruff*, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990). Granting a patent on the discovery of an unknown but inherent function would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art. *In re Baxter Travenol Labs*, 21 USPQ2d 1281 (Fed. Cir. 1991). See M.P.E.P. 2145. On this record, it is reasonable to conclude that the same

patient is being administered the same active agent by the same mode of administration in the same amount in both the instant claims and the prior art reference. The fact that Applicant may have discovered yet another beneficial effect from the method set forth in the prior art does not mean that they are entitled to receive a patent on that method.

Thus, MORGAN teaches, either expressly or impliedly, each and every limitation of the instant claims.

The Examiner advises to add "administering to a patient in need thereof" to distinguish the instant method steps from MORGAN.

Claim Rejections - 35 USC § 103

Claims 13, 61-67, 70, and 76 rejected under 35 U.S.C. 103(a) as being unpatentable over Simeon et a1(1986, Bupropion effects...) in view of Morgan (US6391875, 6274579, 2003/0064988) **are withdrawn** in view of Applicant's amendment.

However, upon further consideration, a new ground(s) of rejection is made as discussed below.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which

said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 13, 61-67, 70, and 76 are rejected under 35 U.S.C. 103(a) as being unpatentable over MORGAN (US 6,274,579) in view of GLENBERG et al (Report on efficacy of treatments for bipolar disorder. Psychopharmacol Bull. 1993;29(4):447-56).

As discussed above, MORGAN teaches a method of treating depression or ADHD (see abstract) which comprised administering to a patient 0.02 to 5mg/kg (see col. 5, line 38-42), in which an average 75kg man would need 1.5-375mg per day, of (S,S)-2-(3-chlorophenyl)-3,5,5-trimethyl-2-morpholinol or salt (see abstract), which is an active metabolite of bupropion (see col. 1, line 48 - col. 2, line 63) , wherein the composition is administered orally (see col. 5, line 59), transdermally (see col. 6, line 18), or buccal (see col. 5, line 60) which would read on mucosally. Additional disclosure includes: pure enantiomers of racemate (see col. 3, line 10-15).

MORGAN does not expressively teach using S,S)-2-(3-chlorophenyl)-3,5,5-trimethyl-2-morpholinol for the treatment of bipolar or maniac condition.

GELENBERG disclosed that bipolar depression have been successfully treated with bupropion (see abstract).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate (S,S)-2-(3-chlorophenyl)-3,5,5-trimethyl-2-morpholinol, which is an active metabolite bupropion, for the treatment of bipolar or manic condition. The person of ordinary skill in the art would have been motivated to make that modification, because the possibility of improved therapeutic effectiveness and safety by reduction of side effects due to lower dose usage for the same outcome,

and reasonably would have expected success because bupropion and its metabolites utilize the same pathways to obtain the same pharmacological effect.

Telephonic Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAKE M. VU whose telephone number is (571)272-8148. The examiner can normally be reached on Mon-Tue and Thu-Fri 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jake M. Vu/

Jake M. Vu, PharmD, JD
Art Unit 1618